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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,873	04/18/2001	David K. Ho	208250	8939

23460 7590 03/03/2003

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EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,873

Applicant(s)

Ho et al.

Examiner

Bruck Kifle, Ph.D.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 11, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90, and 91 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90, and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Applicant's amendments and remarks filed 12/11/02 have been received and reviewed. Claims 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90 and 91 are now pending in this application.

Election/Restriction

The claims still include non-elected subject matter. Applicants are reminded that A is searched on the basis that it represents Gelanamycin. The variable X as amino acid, peptide, polypeptide and protein renders the claims indefinite and will be subject to yet another restriction requirement.

Improper Markush Rejection

Claims 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90 and 91 are again rejected as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables A and X are defined in such a way that they keep changing the core of the compound that determines the classification. By changing the values of X and A, several patentably distinct and independent compounds are claimed. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference.

Limiting the claims to the elected geldanamycin and X as an amino acid side chain selected from those naturally occurring famous 20, would overcome this rejection.

Claim Rejections - 35 USC § 112

Claims 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention. The variable X is defined as being a polar moiety selected from "an amino acid, a peptide, a polypeptide and a protein" which are not radicals but classes of compounds with no open valency. One cannot say where the point of attachment is. Also, hydrogen, methyl, etc. are not polar moieties but are side chains of an amino acid.

Claims 77, 79 and 80 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims have been amended the treating cancers that express Hsp90. There is no indication how one can say whether a given cancer does or does not express Hsp90. If Applicants know which cancers express Hsp90, this should be disclosed. Maybe all cancers express Hsp90. No compound has shown clinical efficacy against all cancers, thus no *in vivo* or *in vitro* assay could be validated for the identification of such a general agent. Applicants' specification logically must lack such assay data.

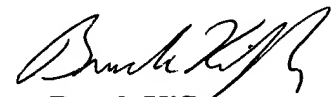
In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

February 28, 2003



Bruck Kifle
Primary Examiner
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